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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,539	01/11/2002	Ambrose L. Cheung	DC-0199	7285

7590 03/18/2004

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EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,539	CHEUNG ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants' election with out traverse of January 12, 2004, 4 is acknowledged. Applicants elected Group VII claims 22-25 which are drawn to a pharmaceutical composition and a method of screening.

Applicants canceled claims, 1-21 and 26-27 which are drawn to non-elected inventions.

2. Currently claims 22-25 are pending and under consideration.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A (1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

4. This application, filed under former 37 CFR 1.60, lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings. In unusual circumstances, the formal drawings from the abandoned parent application may be transferred by the grant of a petition under 37 CFR 1.182.

Specification

5. The disclosure is objected to because of the following informalities:

The use of the abbreviations i.e. SarR and SarA has been noted in this application. Full name and description of these abbreviations are required when they appear first time in the specification.

The use of the trademarks has been noted in this application (i.e. FACscan, MonoQ etc). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening for lead compound which inhibits the expression of virulence determinants in *Staphylococcus* species mainly *Staphylococcus aureus*, does not reasonably provide enablement for all gram positive bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and /or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method of screening for lead compound, which inhibits the expression of virulence determinants in gram-positive bacteria. The specification is only limited to a method of screening for lead compound which inhibits the expression of virulence

determinants in *Staphylococcus aureus* and fails to set forth sufficient evidence showing that the claimed method teach other gram positive organisms.

The specification does not provide substantive evidence that the claimed method is capable of screening for lead compound, which inhibits the expression of virulence determinants in all gram-positive bacteria.

It is well known in the art that different organisms widely differ in pathogenesis, and virulence determinants. Thus screening for lead compound, which inhibits the expression of virulence determinants in different strains of bacteria, is likely complex and a compound that inhibits the expression of virulence determinant in one specific strain or species does not inhibit the expression of virulence determinant in all.

The examples in the instant specification are limited to *Staphylococcus aureus.*

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of organisms broadly encompassed by the claims.

The instant specification invites the skilled artisan to experiment. The factors, which must be considered in determining undue experimentation are set forth in In re Wands USPQ2d 14000.

The factors include

1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art and the
7) breath of the claims.

The instant specification fails to provide a specific methodological procedure for which the

instant method can or is intended to be used for screening for lead compounds which inhibit the expression of virulence determinants in all gram-positive organisms and it fails to mention any other gram-positive organisms beside *Staphylococcus aureus*. With regard to factors three and seven, it is noted that the working examples are limited to *Staphylococcus aureus*. Such is not seen as sufficient to support the breath of the claims, wherein the scope of the claims encompasses all gram-positive bacteria of the instantly claimed method.

It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. see In re Gardner et al. 166 USPQ 138 (CCPA 1970).

8. Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification pages 20-22 (Table 1) recites bacterial strains and plasmids, which has been used for the completion of the instant invention. However, the specification lacks complete deposit information for the deposit of these strains especially RN6390. Because it is not clear that *Staphylococcus aureus* strain possessing the properties of RN6390 and others are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the best mode disclosed by the specification requires the use of RN6390 and others for the production of SarA protein, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above strains especially RN6390, one of skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the strains

especially RN6390 is an unpredictable event. Note that the best mode is not satisfied by a written disclosure unless the exact embodiment is reasonably reproducible from that disclosure. If reproducibility of the above strains especially RN6390 are not established, failure to deposit above strains especially RN6390 would result in concealment of the best mode contemplated by applicant for carrying out the invention. In re Sherwood, 615.2d 809, 204 USPQ 537 (CCPA 1980).

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each nation. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §§1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a

statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) the name and address of the depository,

2) the name and address of the depositor,

3) the date of deposit,

4) the identity of the deposit and the accession number given by the depository,

5) the date of the viability test,

6) the procedures used to obtain a sample if the test is not done by the depository, and

7) a statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the - above strains especially RN6390 described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundeck, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §§1.801-1.809 for further information concerning deposit practice.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 23 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

How the lead compound is identified?

How the heterodimers are formed?

Claims 22 and 23 recite the limitation "the expression of virulence " in line 1. There is insufficient antecedent basis for this limitation in the claims.

It is not clear what the applicants intend in recitation of the phrase " sufficient to allow" in claims 22 and 23.

Claims 22, 23 and 25 recite abbreviations "SarA" and "SarR". Full name and description of these abbreviations are required when they appear first time in the claims.

The term "capable" in claim 25 is a relative term, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheung et al. (US 5,976,792).

Claims 22-25 are drawn to a method of screening for lead compounds, which inhibit the expression of virulence determinants in a gram positive bacteria comprising identifying chemical entities having similarities to SarA protein.

Cheung et al. disclose a method of screening for lead compounds, which inhibit the expression of virulence determinants in a gram-positive bacteria comprising identifying chemical entities having similarities to SarA protein (see column 10, lines 60-65).

Cheung et al. teach Sar A and analogs (See column 5, detailed description of invention and claims) including pharmaceutical compositions. Cheung et al. disclose Sar proteins and the genes encoding such proteins (see column 1). Cheung et al. also teach Sar R and A mutants (see column 12 lines 45-65). The prior art teach the claimed invention.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645
March 15, 2004

RODNEY P SWARTZ, PH.D.
PRIMARY EXAMINER